

Second Regular Session  
Seventieth General Assembly  
STATE OF COLORADO

DRAFT  
1.8.16

DRAFT

LLS NO. 16-0081.01 Christy Chase x2008

HOUSE BILL

HOUSE SPONSORSHIP

Ginal,

SENATE SPONSORSHIP

Newell and Roberts, Aguilar, Kefalas

**BILL TOPIC:** "Drug Production Costs Transparency Requirements"

**DEADLINES:** Finalize by: JAN 14, 2016 File by: JAN 19, 2016

A BILL FOR AN ACT

101 CONCERNING A REQUIREMENT THAT DRUG MANUFACTURERS REPORT  
102 PRODUCTION COSTS FOR CERTAIN HIGH-COST PRESCRIPTION  
103 DRUGS.

Bill Summary

*(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at <http://www.leg.state.co.us/billsummaries>.)*

The bill requires a drug manufacturer that produces a prescription drug made available in Colorado and for which the wholesale acquisition cost equals or exceeds \$50,000 per year or per course of treatment to submit a report to the Colorado commission on affordable health care (commission) detailing the production costs for the drug. The report is to

include:

- Costs for research and development;
- Clinical trials and regulatory costs;
- Costs for materials, manufacturing, and administration attributable to the drug;
- Costs paid by another entity, including grants, subsidies, or other support;
- Acquisition costs, including patents and licensing costs;
- Marketing and advertising costs.

Additionally, a manufacturer must report the cumulative annual history of increases in the average wholesale price and wholesale acquisition cost of the drug, the total company profits attributable to the drug, and the total amount of financial assistance the manufacturer has provided through patient prescription assistance programs.

Manufacturers must submit the report to the commission by August 1, 2016.

By June 1, 2016, the commission must develop a form for manufacturers to use to submit the report. Additionally, the commission is to submit a report to the general assembly by December 1, 2016, that outlines the information reported by drug manufacturers and contains any recommendations the commission may have regarding legislative, administrative, or other policy changes based on the data received from drug manufacturers.

---

1 *Be it enacted by the General Assembly of the State of Colorado:*

2 **SECTION 1.** In Colorado Revised Statutes, **add** article 48 to title  
3 25 as follows:

4 **ARTICLE 48**

5 **Drug Pricing Transparency**

6 **25-48-101. Short title.** THE SHORT TITLE OF THIS ARTICLE IS THE  
7 "DRUG PRICING TRANSPARENCY ACT OF 2016".

8 **25-48-102. Legislative declaration.** (1) THE GENERAL ASSEMBLY  
9 FINDS AND DECLARES THAT:

10 (a) THE INTENT OF THIS ACT IS TO MAKE INFORMATION AVAILABLE  
11 TO THE PUBLIC ABOUT THE COST OF HIGH-PRICED PHARMACEUTICALS IN  
12 ORDER TO MAKE PHARMACEUTICAL PRICING AS TRANSPARENT AS THE

1 PRICING IN OTHER SECTORS OF THE HEALTH CARE INDUSTRY.

2 (b) TO FULFILL THIS GOAL, AS WELL AS TO AID POLICYMAKERS,  
3 GOVERNMENT AGENCIES, AND OTHERS IN UNDERSTANDING THE COSTS OF  
4 PHARMACEUTICALS, IT IS NECESSARY TO REQUIRE DRUG MANUFACTURERS  
5 THAT MAKE THEIR PRODUCTS AVAILABLE IN COLORADO TO REPORT COST  
6 DATA FOR THEIR MOST EXPENSIVE DRUG PRODUCTS.

7 **25-48-103. Definitions.** AS USED IN THIS ARTICLE, UNLESS THE  
8 CONTEXT OTHERWISE REQUIRES:

9 (1) "COMMISSION" MEANS THE COLORADO COMMISSION ON  
10 AFFORDABLE HEALTH CARE CREATED IN SECTION 25-46-103.

11 (2) "DRUG MANUFACTURER" MEANS A MANUFACTURER OF A  
12 QUALIFYING PRESCRIPTION DRUG THAT IS MADE AVAILABLE IN COLORADO.

13 (3) "QUALIFYING PRESCRIPTION DRUG" MEANS A PRESCRIPTION  
14 DRUG THAT HAS A WHOLESALE ACQUISITION COST OF FIFTY THOUSAND  
15 DOLLARS OR MORE ANNUALLY OR, IF THE AVERAGE COURSE OF  
16 TREATMENT FOR A PATIENT IS LESS THAN ONE YEAR, FIFTY THOUSAND  
17 DOLLARS OR MORE PER COURSE OF TREATMENT.

18 (4) "WHOLESALE ACQUISITION COST" MEANS THE COST TO  
19 PURCHASE, PRODUCE, OR ACQUIRE A PRESCRIPTION DRUG AT WHOLESALE.

20 **25-48-104. Reporting requirement.** (1)(a) BY AUGUST 1, 2016,  
21 A DRUG MANUFACTURER SHALL FILE A REPORT WITH THE COMMISSION IN  
22 ACCORDANCE WITH THIS SECTION ON THE COSTS FOR EACH QUALIFYING  
23 PRESCRIPTION DRUG. THE REPORT MUST INCLUDE THE FOLLOWING  
24 INFORMATION:

25 (I) THE TOTAL COSTS TO PRODUCE THE QUALIFYING PRESCRIPTION  
26 DRUG, INCLUDING ALL OF THE FOLLOWING:

27 (A) THE TOTAL RESEARCH AND DEVELOPMENT COSTS PAID BY THE

1 DRUG MANUFACTURER AND, SEPARATELY, THE TOTAL RESEARCH AND  
2 DEVELOPMENT COSTS PAID BY ANY PREDECESSOR INVOLVED IN THE  
3 DEVELOPMENT OF THE QUALIFYING PRESCRIPTION DRUG;

4 (B) THE TOTAL COSTS OF CLINICAL TRIALS AND OTHER  
5 REGULATORY COSTS PAID BY THE DRUG MANUFACTURER AND,  
6 SEPARATELY, THE TOTAL COSTS OF CLINICAL TRIALS AND OTHER  
7 REGULATORY COSTS PAID BY ANY PREDECESSOR INVOLVED IN THE  
8 DEVELOPMENT OF THE QUALIFYING PRESCRIPTION DRUG;

9 (C) THE TOTAL COSTS FOR MATERIALS, MANUFACTURING, AND  
10 ADMINISTRATION ATTRIBUTABLE TO THE QUALIFYING PRESCRIPTION DRUG;

11 (D) THE TOTAL COSTS PAID BY ANY ENTITY OTHER THAN THE DRUG  
12 MANUFACTURER OR PREDECESSOR FOR RESEARCH AND DEVELOPMENT,  
13 INCLUDING ANY AMOUNT FROM FEDERAL, STATE, OR OTHER GOVERNMENT  
14 PROGRAMS OR ANY FORM OF SUBSIDY, GRANT, OR OTHER SUPPORT;

15 (E) ANY OTHER COMPONENTS OF THE WHOLESALE COST OF  
16 ACQUISITION OF THE QUALIFYING PRESCRIPTION DRUG, INCLUDING COSTS  
17 TO PURCHASE PATENTS OR FOR LICENSING OR ACQUIRING ANY CORPORATE  
18 ENTITY OWNING ANY RIGHTS TO THE QUALIFYING PRESCRIPTION DRUG;

19 (F) THE TOTAL MARKETING AND ADVERTISING COSTS TO PROMOTE  
20 THE QUALIFYING PRESCRIPTION DRUG DIRECTLY TO CONSUMERS,  
21 INCLUDING COSTS ASSOCIATED WITH DIRECT-TO-CONSUMER COUPONS AND  
22 AMOUNTS REDEEMED; TOTAL MARKETING AND ADVERTISING COSTS TO  
23 PROMOTE THE QUALIFYING PRESCRIPTION DRUG DIRECTLY OR INDIRECTLY  
24 TO PRESCRIBERS; AND ANY OTHER COSTS FOR ADVERTISING THE  
25 QUALIFYING PRESCRIPTION DRUG;

26 (II) A CUMULATIVE ANNUAL HISTORY OF INCREASES IN THE  
27 AVERAGE WHOLESALE PRICE AND WHOLESALE ACQUISITION COST FOR THE

1 QUALIFYING PRESCRIPTION DRUG, EXPRESSED AS PERCENTAGES,  
2 INCLUDING THE MONTHS EACH INCREASE IN EACH CATEGORY TOOK  
3 EFFECT;

4 (III) THE TOTAL PROFIT ATTRIBUTABLE TO THE QUALIFYING  
5 PRESCRIPTION DRUG, BOTH AS A DOLLAR FIGURE AND AS A PERCENTAGE  
6 OF THE TOTAL COMPANY PROFITS THAT WERE DERIVED FROM THE SALE OF  
7 THE QUALIFYING PRESCRIPTION DRUG; AND

8 (IV) THE TOTAL AMOUNT OF FINANCIAL ASSISTANCE THE DRUG  
9 MANUFACTURER HAS PROVIDED THROUGH PATIENT PRESCRIPTION  
10 ASSISTANCE PROGRAMS, IF AVAILABLE.

11 (b) THE DRUG MANUFACTURER SHALL ITEMIZE AND DOCUMENT  
12 THE INFORMATION SPECIFIED IN PARAGRAPH (a) of this subsection (1).

13 (2) A DRUG MANUFACTURER SHALL FILE THE REPORT REQUIRED BY  
14 THIS SECTION WITH THE COMMISSION ON A FORM PRESCRIBED BY THE  
15 COMMISSION. THE COMMISSION SHALL DEVELOP THE FORM AND MAKE IT  
16 AVAILABLE TO DRUG MANUFACTURERS BY JUNE 1, 2016.

17 (3) UPON RECEIPT OF THE REPORTS FROM DRUG MANUFACTURERS,  
18 THE COMMISSION SHALL REVIEW AND ANALYZE THE DATA, AGGREGATE  
19 THE DATA TO DETERMINE ANY TRENDS IN THE VARIOUS COMPONENTS OF  
20 DRUG PRODUCTION COSTS, AND DETERMINE WHETHER THE DATA  
21 SUGGESTS THE NEED FOR ANY LEGISLATIVE, ADMINISTRATIVE, OR OTHER  
22 POLICY CHANGES.

23 (4) BY DECEMBER 1, 2016, THE COMMISSION SHALL ISSUE A  
24 REPORT TO THE HEALTH AND HUMAN SERVICES COMMITTEE OF THE  
25 SENATE AND THE HEALTH, INSURANCE, AND ENVIRONMENT COMMITTEE  
26 AND THE PUBLIC HEALTH CARE AND HUMAN SERVICES COMMITTEE OF THE  
27 HOUSE OF REPRESENTATIVES DETAILING THE INFORMATION SUBMITTED

1 PURSUANT TO THIS SECTION, THE COMMISSION'S ANALYSIS OF THE DATA,  
2 AND ANY LEGISLATIVE, ADMINISTRATIVE, OR OTHER POLICY CHANGES THE  
3 COMMISSION RECOMMENDS BASED ON ITS REVIEW AND ANALYSIS OF THE  
4 DATA SUBMITTED BY DRUG MANUFACTURERS. ADDITIONALLY, THE  
5 COMMISSION SHALL POST THE REPORT PUBLICLY ON ITS WEB SITE.

6 **25-48-105. Repeal.** THIS ARTICLE IS REPEALED, EFFECTIVE JULY  
7 1, 2017.

8 **SECTION 2. Safety clause.** The general assembly hereby finds,  
9 determines, and declares that this act is necessary for the immediate  
10 preservation of the public peace, health, and safety.